MAY - 8 2000

K000420

Premarket Notification [510(k)] Summary

Submitter: American Medical Devices, Inc
1776 Peachtree Street Suite 200 North
Atlanta, GA 30309

Phone: (404) 815-5233
Fax: (404) 873-3582

Official Correspondent: Frank J. Tighe

Trade Name: The RetinaLabs.com, Inc., Silicone Express Pak

Common Name: Infusion Pak

Registration Number: 1063514

Class: Class 2

Class Name: We were unable to find the device listed in the classification regulations, 21 CFR Parts 862-892 [807.87 (c)].

Panel: Ophthalmic

Product Code: MRH

K000420

Device Description: The RetinaLabs.com, Inc. Silicone Express Pak is a sterile tubing set used to infuse viscous silicone oil into the eye during eye surgery. The silicone is not supplied with the pak, but must be purchased from an FDA approved supplier. Please see Device Replica Diagram in Appendix B.

Statement of indications for use. - For infusing silicone oil during vitreoretinal eye surgery.

Substantial Equivalence Comparison

	American Medical Devices Inc.	**Peregrine Surgical**
Materials PVC	**X**	**X**
For Injection of Silicone Oil	**X**	**X**
Sterilization ETO	**X**	**X**

Sterility

The Device will be ETO Sterilized.

The method used to validate the sterilization cycle is AAMI Overkill Method.

Packaging Material: Tyvek Pouch with a Ploymylar Sheath.

The SAL is 10 to the –6.

The maximum levels of residues of **ethylene oxide**: 25 parts per million; **ethylene chlorohydrin:** 25 parts per million and **ethylene glycol:** 250 parts per million.

This device is non-pyrogenic and the LAL Method is used to make that determination.

Pyrogens: We control the manufacturing environment to lessen the likelihood of pyrogen causing bacteria. In addition the LAL Method is used to determine that each lot is non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2000

Frank Tighe
Retinalabs.com
1776 Peachtree Street
Suite 200 North
Atlanta, GA 30309

Re: K000420
Trade Name: Silicone Oil Express
Regulatory Class: II
Product Code: 86MRH (Ophthalmic Infusion Pump)
Regulation: 880.5725
Dated: February 4, 2000
Received: February 8, 2000

Dear Mr. Tighe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K000420

RETINALABS .com

510(k) Number: N/A

Device Name: Silicone Oil Express Pak (Infusion Pak)

Indications For Use: For infusing silicone oil during vitreoretinal eye surgery.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X___
(Per 21 CFR 8O1.109)

OR

Over-The-Counter Use_____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K000420

1776 Peachtree Street • Suite 200 North • Atlanta, Georgia 30309
Toll Free (800) 793-1473 • Direct (404) 443-2831 • Fax (404) 873-3582 • Internet www.RetinaLabs.com